

REMARKS

The present application relates to hybrid maize plant and seed 35Y54. Claims 1-32 are currently pending in the present application. Applicant respectfully requests consideration of the following remarks.

Detailed Action***A. Specification***

Applicant acknowledges the amendment of July 29, 2002 to the specification was not entered because there was no port of entry on page 33 of the specification at line 35 corresponding to the paragraph to be amended. Applicant apologizes for this inadvertent error. The page and line numbers have now been corrected to reference the correct paragraph to be amended.

B. Claim Objections

Applicant acknowledges that the amendments of July 29, 2002 have overcome all outstanding rejections under 35 U.S.C. § 112, except as indicated below.

C. Claims

Applicant acknowledges the addition of new claims 33 through 54, as suggested by the claims faxed by Supervisory Patent Examiner Amy Nelson on August 2, 2002 and again on November 15, 2002 by Examiner David Fox. The new claims do not add new matter as there is literal support for the claims in the originally filed specification (pages 35-47, specification).

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 5-8, 10-19, 21 and 23-32 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 12, 16, 25 and 29, and dependent claims 13-15, 17-19, 26-28, and 30-32, are rejected as indefinite in their recitation of "plant according to claim 2 [or 20] further comprises...transgenes [or genes transferred by backcrossing]". The Examiner continues that the dependent claims fail to further limit the claims from which they depend.

Applicants have canceled claims 12, 16, 25, and 29, and dependent claims 13-15, 17-19, 26-28, and 30-32, thus alleviating this rejection. Applicant has added new claims 33-54 as

suggested by the claims faxed by Supervisory Patent Examiner Amy Nelson. Applicant has defined transgenes in the present application in the paragraph that spans pages 35-36. Applicant respectfully submits the specification supplies an extensive definition and description of 'transgene' and transgenes of interest. (See generally pages 40-46 for an extensive list of potential transgenes.) Applicant also notes, a person having skill in the art could insert a DNA gene into a selected maize plant.

Claims 11, 15, 19, 24, 28, and 32 remain indefinite in their recitation of "very high", "above average", "very good", "low", "strong", "moderate" and "suited" as these terms are unduly narrative and imprecise, and do not clearly set forth the degree of expression of the claimed characteristics or clearly characterize the corn plants exhibiting them.

Applicant has canceled claims 11, 15, 19, 24, 28, and 32, thereby alleviating this rejection. Applicant has added new claims 33-54. There is literal support for the new claims found in the specification on page 3 and beginning on page 35 of the instant specification.

Claims 10, 14, 18, 23, 27 and 31, and dependents, remain indefinite in their recitation of [t]he maize plant breeding program of claim 9 [or 13 or 17 or 22 or 26 or 30]", which is confusing, since the previous claims are drawn to methods rather than breeding programs.

Applicant has now canceled claims 10, 14, 18, 23, 27 and 31, and dependents, thus alleviating this rejection.

Claims 8 and 21 remain indefinite for characterizing the male fertile plant of claim 2 [or claim 20] as male sterile.

Applicant respectfully traverses this rejection. Applicant has now amended claim 8 to read --has been manipulated to be male sterile--, as suggested by the claims faxed by Supervisory Patent Examiner Amy Nelson, thereby alleviating this rejection. Support can be found on page 13 of the specification, wherein it states "[i]t should be understood that the inbred can, through routine manipulation of cytoplasmic or other factors, be produced in male-sterile form. Such embodiments are also contemplated within the scope of the present claims." Further, the specification states hybrid maize seed is typically produced by a male sterility system incorporating manual or mechanical detasseling" (page 2, specification). In addition, the "detasseling process can be avoided by using cytoplasmic male-sterile inbreds" (page 2, specification). As taught in the specification there are several methods of conferring male

sterility. Therefore, Applicant asserts that one skilled in the art would not find the terminology indefinite. In addition, claim 21 has now been canceled, alleviating this rejection.

In light of the above remarks, Applicant submits that claims 5-8, 10-19, 21 and 23-32 and new claims 33-54 clearly define and distinctly claim the subject matter Applicant regards as the invention. Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 8-19 and 21-32 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner asserts that claims 12, 15, 25, 28, and dependents thereon, are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of using the transgenic plants. The Examiner further states that claims 8, 16, 19, 21, 29, 32, and dependents thereon, are broadly drawn to any "single gene conversion" plant comprising one or more traits introgressed into the claimed variety by backcrossing or other traditional means, and methods of using these plants. The Examiner also states claims 9-11, 13-15, 17-19, 22-24, 26-28 and 30-32 are also broadly drawn to any plant produced by crossing the exemplified hybrid line with any of a multitude of non-exemplified plants, or any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners. The Examiner additionally states that claims 8, 12-19, 21 and 25-32 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner continues, stating that no guidance has been provided for the description, characterization, or isolation of a multitude of heterologous coding sequences conferring a multitude of traits or for the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny. Given the claim breadth and lack of guidance, the Examiner states the specification fails to provide an adequate written description of the genus as broadly claimed.

Applicant has now canceled claims 9-19 and 21-32 and added new claims 33-54 as suggested by the claims faxed by Supervisory Patent Examiner Amy Nelson, thereby alleviating

this rejection. Applicant believes the new claims come within the purview of the written description requirement and do not add new matter. There is literal support for the new claims found in the specification on page 3 and beginning on page 35 of the instant specification. With the addition of the new claims to the remaining allowable claims 1-7 and 20, and currently amended claim 8, Applicant has identified a transgenic 35Y54 plant (claims 33-36), a 35Y54 plant further comprising genes transferred by backcrossing (claims 37-40), or a maize plant wherein at least one ancestor is maize variety 35Y54 (claim 39, for example) by defining a particular threshold that limits variation and reciting a functional test to identify such plants.

Furthermore, Applicant asserts the specification supplies an extensive definition and description of 'transgene' and transgenes of interest. (See generally pages 40-46 for an extensive list of potential transgenes.) Applicant also notes a person having skill in the art could insert a DNA gene into a selected maize plant. Applicant has defined transgenes in the present application in the paragraph that spans pages 35-36 as follows:

With the advent of molecular biological techniques that have allowed the isolation and characterization of genes that encode specific protein products, scientists in the field of plant biology developed a strong interest in *engineering the genome of plants to contain and express foreign genes, or additional genes* (perhaps driven by different promoters) in order to alter the traits of a plant in a specific manner. *Such foreign, additional and/or modified genes are referred to herein collectively as "transgenes".* Over the last fifteen to twenty years several methods for producing transgenic plants have been developed, and *the present invention, in particular embodiments, also relates to transgenic versions of the claimed hybrid 35Y54.*

(emphasis added) The present application clearly describes and defines a transgene to be a gene transferred into a plant wherein the product of that gene is expressed. This expression will confer a new or improved trait into that plant. In addition, Applicant respectfully submits that "[t]he test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. . . . If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. . . . The degree of precision necessary for adequate claims is a function of the nature of the subject matter." Miles Laboratories, Inc. v. Shandon Inc., 997 F.2d 870 (Fed. Cir. 1993).

The Examiner also asserts that Hunsperger et al., Kraft et al., and Eshed et al. teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant

genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype is said different plant.

Applicant respectfully traverses these rejections. Applicant respectfully submits that Hunsperger et al. does not teach what the Examiner proposes in column 3, lines 26-46. On the contrary, Hunsperger et al. teaches that the allelic DNA genetic factor that results in dwarfism of a petunia plant as disclosed has been incorporated into other genetic backgrounds of the petunia species. (See column 2, line 67 to column 3, lines 1-4). Therefore, the Examiner has not shown that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization is unpredictable. Further, in Eshed et al., the reference specifically states that "maize did not show a less-than-additive trend" (page 1816, column 1, lines 1-5). In addition, Applicant's disclosure is sufficiently enabling because the specification describes transformation of hybrid maize 35Y54 starting on page 35. The advent of molecular biology techniques have allowed isolation and characterization of genes that encode specific proteins. On page 40, second full paragraph, Applicant discloses that for a transgenic plant, which shows high levels of expression, a genetic map can be generated to identify approximate chromosomal locations of integrated DNA. Such methods are incorporated by reference. Thus, Applicant provides a sufficient enabling disclosure for those skilled in the art to generate the 35Y54 plant with a transgene. Applicant may create genetic maps to identify the integrated DNA, which would assist in determining introgression. Furthermore, on page 40 of the instant specification, Applicant discloses that plants can be genetically engineered to express various phenotypes of agronomic interests. The detailed description for such changes as indicated are shown for example, for those which confer resistance to pests or disease (page 40), resistance to herbicides (page 43) or genes to confer value-added traits (page 44). Applicant then discloses on page 45 methods for 35Y54 transformation. Moreover, on page 46, following transformation of the 35Y54 plant, target tissue expression of the selectable marker genes as described in the specification allow the "preferential selection of transformed cells, tissues, and/or plants using regeneration and selection methods", which are well-known in the art. Such predictability refers to the ability of one skilled in the art to extrapolate the disclosed or known results of the claimed invention. Applicant's disclosure enables one skilled in the art following transformation to preferentially select the transformed cells using selectable markers. Applicant respectfully requests Examiner to withdraw this rejection.

The Examiner also asserts Kraft et al. teaches, for example, that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature, that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of breeding materials, and therefore it is an unpredictable effect in plant breeding, on page 323 of the reference, column 1, lines 7-15. The Examiner continues that given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate the genes responsible for a multitude of non-exemplified traits, to evaluate the ability of these genes to be successfully expressed in various maize genetic backgrounds, or to obtain "single gene conversion" plants which contain a multitude of introgressed traits, but otherwise maintain all of the genetic and physiological and morphological characteristics of the parent plant.

Again, Applicant respectfully submits that Kraft et al. does not stand for the proposition for what the Examiner is asserting. The Examiner states "that very little is typically known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, line 7 to line 15)." This section is taken from Kraft et al. at page 323 column 2, lines 5-8, where Kraft et al. is merely stating that "very little is known about the distances spanned by linkage disequilibria in breeding materials", not that little is known about plant breeding materials. It is also important to note that Kraft et al. relates to linkage disequilibrium and fingerprinting in the sugar beet, a crop other than maize. Kraft et al. simply teaches that they found an increase in linkage disequilibrium for tightly linked markers in sugar beets (see page 324, column 2, lines 2-15). Further, the reference teaches that mapped position of markers are not useful for discerning distances between two lines where the levels of linkage disequilibrium is low, particularly in well-defined heterotic groups (see page 326, column 1, lines 1-11). The cited reference also specifically states that "[t]he generality of our results for other crop species needs to be investigated" (page 326, column 1).

Finally, as provided in 37 C.F.R. §§ 1.801-1.809, Applicant wishes to reiterate they will refrain from deposit of Hybrid 35Y54 until allowable subject matter is indicated. Once such notice is received, an ATCC deposit will be made, and the specification will be amended to contain the accession number of the deposit, the date of the deposit, a description of the deposited biological material sufficient to specifically identify it and to permit examination and

the name and address of the depository. The claims will also be amended to recite the ATCC deposit number. In addition, Applicant submits that at least 2,500 seeds of Variety 35Y54 will be deposited with the ATCC. Therefore, Applicant asserts the written description requirement set forth in 35 U.S.C. § 112 will then be met, particularly in light of the fact that Applicant will have reduced the invention to practice and deposited the derived biological materials in a public depository, thereby demonstrating its "possession" of the invention. Enzo Biochem Inc., v. Gen-Probe, Inc., 63 U.S.P.Q.2d (BNA) 1609, 1613 (Fed. Cir. 2002) ("In light of the history of biological deposits for patent purposes, the goals of the patent law, and the practical difficulties of describing unique biological materials in a written description, we hold that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, 1."); see also MPEP § 2163.02 (8th ed. Aug. 2001) ("Under Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.") Moreover, the majority of claims are now in proper method format whereby by deposit of hybrid 35Y54 and through the description of well known methods in the art, Applicant is unsure the basis for lack of written description. In view of this assurance, the rejection under 35 U.S.C. § 112, first paragraph, should be removed (MPEP § 2411.02). Such action is respectfully requested.

In light of the above remarks, cancellation of claims 9-19 and 21-32, and addition of new claims 33-54, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Issues Under 35 U.S.C. § 102/103

The Examiner rejects claims 11, 15, 19, 24, 28, and 32 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Dowden (U.S. Patent 5,880,339).

Applicant has canceled claims 11, 15, 19, 24 and 32 and added new claims 33-54 as suggested by the claims faxed by Supervisory Patent Examiner Amy Nelson on August 2, 2002

and again on November 15, 2002 by Examiner David Fox, thus alleviating this rejection. Moreover, Applicant claims a method of making a plant which did not previously exist. Pursuant to the recent Federal Circuit decision, Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research, 304 F.3d 1221, (Fed. Cir. 2002), "a novel patented product is not "anticipated" if it did not previously exist." Id. This is the case whether or not the process for making the new product is generally known. Id. The invention 35Y54 has not previously existed as it is the result of crossing two maize inbred lines GE570932 and GE486862.

In light of the above, Applicant respectfully requests the Examiner withdraw the rejection to claims 11, 15, 19, 24, 28, and 32 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Dowden (U.S. Patent 5,880,339).

Applicant acknowledges that claims 1-7 and 20 are allowed. Applicant further acknowledges that claims 1-10, 12-14, 16-18, 20-23, 25-27 and 29-31 are free of the prior art, given the failure of the prior art to teach or suggest the particularly claimed maize plants with their unique complement of genotypic and morphological characteristics, or methods of using them. This clearly indicates that the hybrid 35Y54 as a whole is considered distinguishable from the prior art for the purposes of novelty and non-obviousness. In light of the above, Applicant respectfully requests reconsideration and withdrawal of the rejections.

Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested.

No additional fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



Lila A. T. Akrad, Reg. No. 52,550
McKEE, VOORHEES & SEASE
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309-2721
Phone No. (515) 288-3667
Fax No. (515) 288-1338
CUSTOMER NO: 27142

Attorneys of Record

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